

REMARKS

As a preliminary matter, Applicants thank the Examiner for withdrawing the prior objections and/or rejections.

Claims 9-19 are pending in this application. No new matter has been added. Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

CLAIMS

I. Rejection of claims 11-19 under 35 U.S.C. §§ 102(e) and 103(a) based upon Turner et al., U.S. Patent Pub. Appl. No. 2002/0137894.

In the Office Action, claims 11-19 were rejected under 35 U.S.C. § 102(e), as allegedly anticipated by Turner *et al.* (U.S. Patent Pub. Appl. No. 2002/0137894, hereinafter Turner) or in the alternative under 35 U.S.C. § 103(a) as obvious being over Turner. Claims 16 and 18 have been cancelled. The Examiner alleges that while Turner does not provide express examples of each embodiment of the present application, Turner teaches recombinant or genetically engineered MSFs for intracellular expression in a number of host cells. Applicants respectfully traverse the rejections on three grounds.

First, as the Examiner admits, Turner does not provide examples of each embodiment or element of the present invention. As stated in § 2131, of the M.P.E.P.: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Turner does not mention or describe SZP and therefore cannot anticipate the element of claim 11 that requires: “isolating the SZP from the cell or culture medium.” Taking into account the Examiner’s observation that “Turner does not provide express examples of each embodiment encompassed by the claims,” Applicants contend that Turner cannot anticipate the present invention under 35 U.S.C. §102(e) and thus now address the Examiner’s alternative grounds for rejection under 35 U.S.C. §103(a).

Second, Applicants respectfully submit that a *prima facie* case of obviousness has not been established as required under 35 U.S.C. §103(a), the Examiner's alternative grounds for rejection of claims 11-19. As stated in § 2143 of the M.P.E.P.,

[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Applicants submit that the combination of prior art references fails to teach or suggest all the elements of the claimed present invention. First, the Examiner has alleged that the MSFs as disclosed in Turner are the same as SZP claimed in the present invention. Applicants point to the Examiner's reference to a publication by Flannery *et. al.* (*Biochem. Biophys. Res. Commun.* 254(3):535-541 (1999), IDS, hereinafter Flannery) in the other 35 U.S.C. §103(a) rejection of the current office action. (See discussion below). In that reference Flannery states that "SZP is homologous to the precursor protein of a megakaryocyte stimulating factor (MSF)...” P. 536. Hence it may be readily concluded from that statement that SZP and MSF are not equivalent, but rather that SZP is equivalent to a protein that is a precursor of MSF. Because SZP and MSF are not equivalent, Turner cannot anticipate, under 35 U.S.C. § 102(e), or make obvious, under 35 U.S.C. §103(a), the present invention.

Third, the Examiner has further alleged that claim 18 is an inherent property of SZP. However, Applicants respectfully submit that the subject matter of claims 16 and 18 is illustrative of the fact that the methods of Turner do not anticipate or make obvious the methods of the present invention. The molecular weights claimed in claims 16 and 18 are vastly different from those molecular weights reported in Turner. In fact, the molecular weights of the SZP cited in claims 16 and 18 are “about 110kDa” and “greater than 280kDa,” respectively, while the MSFs of Turner range from 13.2kD to about 50kD. In the application as originally filed,

Applicants have shown the “SZP lacking glycosylation preferably has a molecular weight of about 110kDa,” and that “[i]n other embodiments, the isolated SZP or fragment or derivative is glycosylated, preferably having a molecular weight of greater than 280kDa.” P. 29, lines 15-18. Specifically, Turner discloses, and lists, specific sequences for MSFs with molecular weights of 11.6 and 19kD (paragraph [0064]), 20-50kD (paragraph [0065]), 13.2 and 21kD (paragraph [0066]), 16.2 and 23.5kD (paragraph [0067]), and 18.4 and 27kD (paragraph [0068]). While the molecular weight of a given protein produced by a given method may be an inherent property of the method, here it is concrete evidence that the methods of Turner and the present invention are not the same. If the methods were the same, then Turner would have found materials with molecular weight in excess of “about 110kDa, 120kDa, 130kDa, 140kDa,” as in claim 16 and page 29, line 16, or “greater than 280kDa,” as in claim 18. Without a showing that the MSFs in Turner have the same molecular weight of the SZP in the present invention, Turner cannot anticipate, nor make obvious the claims of the present invention.

Applicants respectfully request that the Examiner withdraw the rejection of claim 11. Furthermore, because claims 12-19 are dependent upon claim 11, and thereby include the elements of claim 11, Applicants request that the Examiner withdraw the rejection of those claims as well.

II. Rejection of claims 9 and 10 under 35 U.S.C. § 103(a), based upon Flannery *et al.*, in view of Adkisson *et. al.*

In the Office Action, claims 9 and 10 were rejected under 35 U.S.C. § 103(a), as allegedly obvious over Flannery in view of Adkisson *et. al.* (US Pat. No. 6,654,764, hereinafter Adkisson). The Examiner states that Flannery teaches that SZP may be purified from bovine chondrocytes cultured in 5% solution of serum. The Examiner further states that the media were harvested and the SZP purified. The Examiner then alleges that while Flannery does not teach the use of serum free media, Adkisson provides the motivation to culture chondrocytes under serum free conditions. Applicants respectfully traverse the rejection of claims 9 and 10.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established for the following reasons. First, Applicants submit that the combination of prior art references fails to teach or suggest all the elements of the claimed present invention. The Examiner admits that Flannery fails to teach or suggest each and every element of claim 9, specifically the use of serum-free medium for the expression of SZP and isolation of the SZP from the medium. Flannery does not teach or suggest serum-free medium and Adkisson does not mention or describe SZP or MSF. That Adkisson may disclose culturing chondrocytes under serum free conditions without any reference to SZP or MSF is insufficient motivation to combine with Flannery, which does not use serum free media. Without more, Applicants submit that there does not appear to be any suggestion or motivation to combine the two references, and as such, Flannery and Adkisson cannot serve as the basis for a rejection under 35 U.S.C. § 103(a). Applicants request that the Examiner withdraw the rejection of claim 9.

Second, Applicants assert that in regard to claim 10, a dependent claim of claim 9, the combination of Flannery and Adkisson does not teach or suggest every element of the claimed invention. The Examiner has not asserted any grounds for rejecting claim 10, other than stating that it is unpatentable over Flannery in view of Adkisson. However, Applicants assert that neither Flannery nor Adkisson mentions or describes the use of immortalized cells for the production of any proteins, much less the production of SZP. Because even the combination of Flannery and Adkisson fails to teach or suggest all of the elements of claim 10, Flannery and Adkisson cannot serve as the basis for the rejection of claim 10 under 35 U.S.C. § 103. Therefore, Applicants respectfully request the Examiner withdraw the rejection of claim 10.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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